

Remarks

Claims 72-89 are pending in the subject application and currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the rejection under 37 CFR § 1.75(e).

Claims 72-89 remain rejected under 35 U.S.C. § 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility. In addition, claims 72-89 remain rejected under 35 U.S.C. § 112, first paragraph, as nonenabled on the grounds that the subject specification fails to teach a substantial utility for the claimed invention and, therefore, an ordinarily skilled artisan would not know how to use the claimed invention.

In maintaining the rejection of record, the Office Action argues:

The specification discloses that the polypeptides of the invention are homologous to COL8A1, COL8A2, CORS-26 and BAFF (respectfully, it is noted that the fact that the instant protein is homologous to 4 different proteins further demonstrates that Applicants have not clearly characterized the instant protein). Based on the structural similarity, the specification asserts that the newly disclosed INSP164 has similar activities. The assertion that the disclosed proteins have biological activities similar to known proteins (COL8A1, COL8A2, CORS-26 and BAFF) cannot be accepted in the absence of supporting evidence, because generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases.

In support of this position, the Office Action cites to a number of references (Skolnick *et al.*, Bork *et al.*, Doerks *et al.* and Brenner *et al.*), the most recent of which was published in 2000 (Bork *et al.*). Applicants submit, herewith, a Journal of Molecular Biology article (Wilson *et al.*, 2000, *J. Mol. Biol.*, Vol. 297, pp. 233-249) published in the same timeframe as the references cited in support of the rejection of record. As opposed to the broad and sweeping generalizations found in Skolnick, *et al.*, Bork *et al.*, Doerks *et al.* and Brenner *et al.*, the claimed polypeptide was identified utilizing a program (GENOME THREADER) that identified INSP163 as a member of the TNF family of polypeptides (see, for example, page 10, last paragraph and page 26, last paragraph discussing GENOME THREADER and the PCT application disclosing the program and database). As noted in the specification, the claimed polypeptide was assessed to be a member of the TNF family of

proteins with a relatively high degree of confidence (68-84% confidence, see Example 1). For the convenience of the Examiner, a number of the proteins identified in the GENOME THREADER analysis are attached to this response. This is also discussed at pages 11-12 of the as-filed specification where the similarity of the claimed polypeptide to TNF related proteins is discussed. Indeed, a common thread shared by the vast majority of the proteins discussed at pages 11-15 is their involvement in inflammatory disorders, such as arthritis. Applicants further note that TNF and TNF-like proteins had been art recognized to be associated with arthritis and other types of inflammatory disorders (see, for example, pages 14-15 of the as-filed specification discussing the role of BAFF (a TNF-like protein) in various inflammatory disorders). Thus, one skilled in the art would have reasonably expected the claimed polypeptide to be involved in an inflammatory disorder, such as arthritis, on the basis of the function assigned to the polypeptide by GENOME THREADER.

Applicants also note that the Office Action argues that even if the Examiner accepted the asserted utility of the claimed polypeptide as being associated with arthritis and/or osteoarthritis, the Examiner would not find that such a use was supported by the instant application. Applicants respectfully submit that the use of the information in the co-pending application is permissible as evidence that a disclosed invention is operable or as evidence to demonstrate the objective truths of statements provided in the as-filed specification (see *In re Marzocchi*, 439 F.2d 220, 223 n.4, 169 U.S.P.Q. 367, 370 n.4 (C.C.P.A. 1971). In this case, the later filed application provides evidence that overexpression of INSP-163 mRNA is associated with osteoarthritic tissues and lung cancer, thus supporting the asserted utility of the claimed polypeptide as being useful for the identification of various diseases, such as arthritis or osteoarthritis. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claims 72-89 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 44, 46 and 47 of copending Application No. 11/912,432. Applicants respectfully request that this matter be held in abeyance until such time as allowable subject matter is identified. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Wilson *et al.*, 2000

Three proteins identified in the GENOME THREADER analysis